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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,872	09/30/2003	Galina Fomovskaia	56075-PCT-CIP-C (45858)	7999
21874	7590	08/21/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,872

Applicant(s)

FOMOVSKAIA ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-36 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 18-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-04; 9/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 4-8 and 12-17 in the reply filed on 7/13/2006 is acknowledged. The traversal is on the ground(s) that there is significant overlap in the subject matter of the claims and therefore, does not constitute a burden to the Examiner. Applicant states that if the Examiner is aware of another method to make the product as claimed, using a process which is materially different from that set forth in the restricted claims, applicant respectfully request the Examiner substantiate her position in greater detail. Applicant states that otherwise, it is respectfully requested that the restriction requirement be withdrawn, and that each of claims 4-36 presently pending in this application be examined.

2. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In response to Applicant arguments, the Examiner maintains that the claims would impose a serious burden to the examiner if search together because the searches of the different inventions are not coextensive because the different inventions encompass an extensive search of patent and non-patent literature that may teach the dry substrate irrespective of the manner in which it is used. For, example a search of a "dry substrate" as recited in the invention of Group I on one database resulted in over 14000 hits. In response to Applicant's arguments for the Examiner to provide evidence of another means of making the product of invention I, it is noted that none of the claims recite "a method of making a dry substrate" but rather recites "a method of using a dry substrate".

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MPEP 806.05(h) [R-3] states that "[A] product and a process of using the product can be shown to be distinct inventions if *either or* both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) *the product as claimed can be used in a materially different process*. The burden is on the examiner to provide an example, but the example need not be documented. If the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement."

In this case, the prior Office action clearly provides several examples wherein the product of invention I can be used in a materially different process. As stated in the prior Office action, the product of Invention I can be used in the storage and collection of genetic material (US 5756126 teaches the use of a dry solid medium for use in the storage and collection of genetic material), rather than in the lyses and purification of nucleic acids as claimed.

The requirement is still deemed proper and is therefore made FINAL. Accordingly, claims 4-8 and 12-17 are addressed in this Office action. Claims 9-11 and 18-36 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(a) Claim 5 lacks proper antecedent basis for "said indicator means" because the claim 1 from which it depends do not recite "an indicator means", but recite "an indicator". It is suggested amending the claims such that the claim language agrees.

Claim Rejections - 35 USC § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 4-8 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloch et al., {Bloch, herein} (US 4,789,630, December 1988). Regarding claims 4 and 5, Bloch teaches a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon (col. 17, lines 63-64); a coating, wherein the coating comprises an anionic surfactant or detergent capable of cellular lysis (col. 14, lines 8-14 and 56-64); and an indicator for indicating the presence of nucleic acid, which is maintained on the solid support, wherein said indicator is a color indicator or fluorescent indicator (col. 31, lines 9-18; see also, col. 23, lines 39-47 and col. 11, lines 28-30).

Regarding claim 6, Bloch teaches the substrate of claim 4, wherein the substrate is in a shape from the group consisting essentially of a sheet or ball (col. 8, lines 9-10 col. 12, lines 21-22 and col. 17, lines 54-58).

Regarding claim 7, Bloch teaches the substrate of claim 6, wherein said substrate further includes an integrity maintenance means (col. 35, line 68 to col. 36, line 1).

Regarding claim 8, Bloch teaches the substrate of claim 7, wherein said substrate is a sheet (membrane), said integrity maintenance means is a plastic bag (see col. 35, line 68 to col. 36, line 1).

Regarding claim 12, Bloch teaches a kit comprising a dry substrate consisting: a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon (col. 17, lines 63-

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64); a coating, wherein the coating comprises an anionic surfactant or detergent capable of cellular lysis (col. 14, lines 8-14 and 56-64); and an indicator for indicating the presence of nucleic acid, which is maintained on the solid support, wherein said indicator is a color indicator or fluorescent indicator (col. 31, lines 9-18; see also, col. 23, lines 39-47 and col. 11, lines 28-30) and integrity maintenance means (col. 35, line 68 to col. 36, line 1).

Regarding claim 13, Bloch teaches the kit of claim 12, wherein the coated matrix is in a shape from the group consisting essentially of a sheet or ball or dipstick (swab) (col. 8, lines 9-10; col. 12, lines 21-22 and col. 17, lines 54-58).

Regarding claim 14, Bloch teaches the kit of claim 12, wherein said coated matrix is in a shape selected from the group consisting essentially of a plastic bag (col. 35, line 68 to col. 36, line 1) or cellophane and parafilm¹ (col. 8, lines 9-10; col. 12, lines 21-22 and col. 17, lines 54-58).

Regarding claims 15, Bloch teaches a substrate consisting of a matrix, a coating and integrity means (see col. 23, lines 39-47 and col. 11, lines 28-30; col. 35, line 68 to col. 36, line 1; see also col. 11, line 45 to col. 12, line 35, which further teaches plastic sheet having coating attached).

Regarding claims 16 and 17, Bloch teaches a card (sheet or paper) comprising a matrix, coating, an integrity maintenance means and indicator means, said card can further comprises blood (col. 17, lines 52-57; col. 18, lines 3-6; col. 23, lines 39-56). Therefore, Bloch meets the limitations of the claims recited above.

Claim Rejections - 35 USC § 102(b)

6. Claims 4-8 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgoyne (US 5,496,562, March 1996). Regarding claims 4 and 5, Burgoyne teaches a dry substrate consisting of a solid matrix comprises a cellulose-based paper (nitrocellulose) (col. 2, lines 21-25); a coating, wherein the coating comprises an anionic surfactant or detergent (col. 2, lines 59-64) and an indicator, which is maintained on the solid matrix, wherein the indicator is a color indicator (ink stamp or pencil marking) (col. 8-15).

Regarding claim 6, Burgoyne teaches wherein said substrate is a sheet (filter) or card (col. 2, lines 21-23 and col. 4, lines 61-65).

Regarding claim 7, Burgoyne teaches wherein the substrate further includes an integrity maintenance means (col. 3, lines 1-6).

Regarding claim 8, Burgoyne teaches wherein said substrate is a sheet (filter) and said integrity maintenance means is a plastic bag (plastic encasing (col. 3, lines 1-6).

Regarding claims 15 and 16, Burgoyne teaches a substrate or blood card consisting of a matrix, a coating and integrity maintenance means (Col. 2, lines col. 47-64; col. 3, lines 1-6 and Example 2).

Regarding claim 17, Burgoyne teaches wherein the blood card further includes an indicator means for indicating the presence of nucleic acid (col. 5, line 8-15). Therefore, Burgoyne meets the limitations of the claims of the instant invention.

¹ It is unclear applicant's intent in regards to the shape of cellophane and parafilm. Accordingly, the Examiner is interpreting the shape of cellophane and parafilm to be in reference to a sheet.

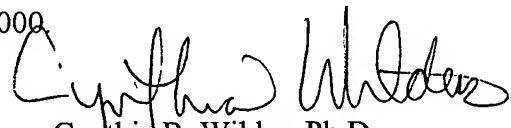
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Conclusion

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637

8/17/2006